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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,428	08/07/2001	Lei Wu	4718420005000	3614
25225	7590	09/30/2004	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			CHEU, CHANGHWA J	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,428

Applicant(s)

WU ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/26/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-14, 16-20, 25-31, 33-93, 95-114 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95 and 115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 7/21/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 15, 21-24, 32 and 94 are cancelled.
2. Claims 5 and 116 are amended.
3. Currently, claims 1-14, 16-20, 25-31, 33-34, 56-57, 67-68, 92-93, 95 and 115-116 are pending and under examination. Claims 35-55, 58-66, 69-91, 96-114 are withdrawn from further consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1-2, 5, 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al (US 5120662), Tiffany et al. (US 5508200), or Liotta et al. (US 5942407) in view of Dames et al. (WO 00/16893).

The aforementioned prior art, *each individually*, teaches features recited in the instant invention, including a device comprising a substrate, a photorecognizable coding pattern on the substrate (e.g. bar code), a binding partner capable of binding to a moiety to be manipulated and no need of anodized metal surface layer.

For Chan et al. reference, see Figure 11, where the binding layer (component 84) as substrate for binding partner, and photorecognizable bar code (component 94) is on the substrate.

For Tiffany et al. reference, see Figure 2, where component 17 is a substrate which can be bound to binding partners, and component 10 is a photorecognizable bar code (Col. 5, line 25-37).

For Liotta et al. reference, see Figure 1A-1B, where layer 10 is a substrate containing binding partner ligand, and bar code photorecognizable pattern (Figure 5, Col. 15, line 17-25; Col. 17, line 25-30).

However, no feature of "photorecognizable coding pattern comprising a hole not penetrating through the entire of said substrate" is taught by the above Chan, Tiffany, and Liotta et al. references. Nevertheless, Dames et al. teach a micro-label design to identify analyte of interest in a solution. Dames et al. teach using a photorecognizable coding pattern on a substrates, i.e. bar code formed by a series of holes on the metal layer. (See page 3, line 26-29) The device taught by Dames et al. provide a low-cost, fast and convenient manner for identifying purposes through flow cytometry reader system, or fluorescence/imaging microscopy. (See page 2, line 13-15; page 3, line 6-8; claim 14-19) The examiner would like to point out that in combination of Dames et al. teaching, i.e.

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the photorecognizable bar code having holes on the micro-label device, with the references of Chan, Liotta or Tiffany, the bar code would attach on a substrate not penetrating through the depth of the substrate. (See Figure 11 in Chan et al.; Figure 2 in Tiffany; Figure 5 in Liotta) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided either the device of Chan, Liotta or Tiffany with the photorecognizable bar code as taught by Dames et al. for low-cost and convenient identifying analyte of interest in a test sample.

4. Claims 1-6, 11, 16-20, 25-29, 31, 33-34, 56-57, 67-68, 92, 95, 115, 116 are rejected under 35 U.S.C. 102(e) as being unpatentable by Cattell (US 6180351) in view of Dames et al.

Cattell teaches an addressable array of biopolymers, such as DNA probes, on a substrate. (See abstract) The DNA probes are the binding partners which can be manipulated by hybridization binding reaction. The substrates are selected from the group consisting of glass, silicon dioxide (i.e. silica), metals and plastics. (Col. 13, line 65 to Col. 14, line 1-5) Cattell teaches that the substrate surface layer can be modified by adding organic or inorganic layers, and the modified layer thickness can be ranged from 0.1 mm to 1 micron. (Col. 14, line 12-16) The bar code (component 356) is lithographically fabricated on the glass substrate (component 10). (See Figure 1) The bar code substance is deposited on the substrate for photorecognition. (See Figure 1) Cattell also teaches using fluorescent markers for the detection of the binding pattern. (Col. 1, line 22-25) Cattell teaches that the substrate shape may be of any shape. (Col. 7, line 45-46) The device taught by Cattell does not comprise an anodized metal surface layer. With respect to claim 4, the instant claim recites that the surface is either hydrophilic or hydrophobic. Cattell teaches that the surface layer can be modified by either organic or inorganic approaches, therefore would be obvious to one ordinary skilled in the art to modify the surface characteristics into hydrophilic or hydrophobic by adding peptides, proteins, polynucleic acids, polyesters, polyureas, polyimides, and the like, to have better affinity for biological molecules. (Col. 14, line 17-25) However, no feature of "photorecognizable coding pattern comprising a hole not penetrating through the entire of

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said substrate” is taught by Cattell. Dames et al. teach a micro-label design to identify analyte of interest in a solution. Dames et al. teach using a photorecognizable coding pattern on a substrates, i.e. bar code formed by a series of holes on the metal layer. (See page 3, line 26-29) The device taught by Dames et al. provides a low-cost, fast and convenient manner for identifying purposes through flow cytometry reader system, or fluorescence/imaging microscopy. (See page 2, line 13-15; page 3, line 6-8; claim 14-19) The placement of Dames’ photorecognizable bar code on the substrate device taught by Cattell would result in a series of “hole not penetrating through the entire of said substrate”. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided either the device of Cattell with the photorecognizable bar code as taught by Dames et al. for low-cost and convenient identifying analyte of interest in a test sample.

5. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cattell.

Cattell reference has been discussed with respect to the non-specific shapes requirement on the substrate. (Col. 7, line 45-46) However, Cattell reference is silent in specifying the dimensions on the substrates. Nevertheless, it has been held that a change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955) Furthermore, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cattell with alternative size options for the substrates since such manipulations for optimum or workable ranges only involves routine skilled in the art.

6. Claims 12-14, 30 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cattell in view of Zhou et al. (WO 0054882)

Cattell reference has been discussed before but fails to specifically teach using aluminum, magnetic, nickel or CoTaZr alloy. Zhou et al. teach using external active forces, such as

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magnetic manipulation over biochips, for detection of biomolecules with the advantages of microfabrication and microelectronic technologies. (page 5, last paragraph and second paragraph; page 6, first paragraph;) Zhou et al. teach using aluminum as the conductive layers beneath an insulating non-metal layers, and method of obtaining a nickel alloy for the biochip. (page 35, first paragraph; page 29, first paragraph) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Cattell with the metal layers or alloy as taught by Zhou et al, since using the active biochips, e.g. external magnetic forces, providing advantages over the passive biochips in microfabrication and microelectronic technologies.

Response to Applicant's Arguments

Dames et al. reference (WO 00/16893)

7. Applicant argues that the combination of Dames et al. reference with the primary references cited in the previous Office Action, such as Chan et al (US 5120662), Tiffany et al. (US 5508200), or Liotta et al. (US 5942407), would result in a change in the basic principle which the Dames et al's devices were to operate. Particularly, the microfabricated labels taught by Dames et al. having a surface layer of anodized metal, whereas the instant invention, in contrast, having a feature of the photorecognizable coding pattern does not comprise an anodized metal surface layer (See Remarks and Arguments, page 24, second paragraph). Therefore, the combination of the recited references by Examiner would not be permissible to arrive to the claimed invention. Applicant's arguments have been considered but are not persuasive.

Examiner had established that all the Chan, Tiffany, or Liotta et al. having features recited in independent claim 1, including substrate, photorecognizable code pattern on the substrate and binding partners. The mere deficiency for those references rendering obviousness to the claimed invention lie on the feature of "said photorecognizable coding pattern comprises a hole not penetrating through the entire depth of said substrate and said microdevice does not comprise an anodized metal surface." Although Dames et al.

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reference has a feature seemingly contrasting to the instant invention, i.e. the labels with a surface layer of anodized metal, nonetheless this would not be deemed an impermissible combination as alleged by the applicant. Examiner would like to draw applicant's attention that the purpose of using anodizing metal surface is for "attachment of a wide range of biochemically active agents for use as highly selective probe" (See Dames et al. reference, page 2, line 26-30). The anodized surface is not for detection purpose rather it is for attracting biological molecules with negative surface charge. The references of Chan, Tiffany, or Liotta et al. already provided binding moiety for the attachment of target molecule in interest, it is the combination of optical photorecognizable feature taught by Dames et al. render the instant invention obvious because the advantage of cost-effective, time-saving and analogous field of need.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

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September 26, 2004


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09/27/04